

Medical Spas, LASERS, BOTOX

The use of medical lasers, laser-like devices, and intense pulsed light therapy devices may constitute the practice of surgery.

These devices are commonly used for hair removal, wrinkle treatment, dental treatments, eye surgery, surgical knives, spider vein removal and bio-stimulation.

The FDA which regulates radiation-emitting products, documents/defines medical lasers as prescriptive devices available for sale only to licensed practitioners. Medical laser products have been defined by 21 CFR §1040.10(b)(26) as a medical device described in 21 U.S.C. § 321 (h).

The Missouri State Board Registration for the Healing Arts interprets the FDA regulations to require sale of such equipment, only to licensed professionals whose statutory scope of practice authorizes them to perform surgery without supervision.

Presently in Missouri, Medical spas are not licensed by the Department of Health and Senior Services.

Medical Spas can combine several different licensed professions, (physician, nurses, physician assistants, cosmetologist, estheticians, massage therapists, etc.) in one facility. To support consumer safety, the Board of Healing Arts strongly recommends:

- 1) Each medical spa employs a Medical Director. For those facilities utilizing Class III-B and/or Class IV lasers a laser safety officer, is also recommended;
- 2) An informed consent document shall be signed by the patient/client clearly stating the diagnosis, risk/benefit of laser treatment and alternative therapy;
- 3) The patient/client should be provided with the name and qualifications (degree) of the person(s) administering the treatment and directions for contacting personnel for after therapy complications;
- 4) Post the license of the Medical Director in a conspicuous place;
- 5) Post the days/hours the Medical Director is available in the spa.

Class III-B and Class IV laser therapy should be performed under “direct” supervision (physical presence of supervising licensee on premises). Class I, II & III-A laser therapy may be performed under “indirect” supervision however the supervising licensee should be readily available, i.e. within 20 miles or 30 minutes.

Treatment should be performed and limited to individuals qualified by training, skill, competency, age, experience, or licensure.

The use of prescriptive injections, including the injection of “Botox Cosmetic” and “Vistabel” may constitute the practice of medicine. Accordingly, the same statutes and rules would apply to these treatments as are applicable to medical necessity. Licensed personnel would be held to the identical standards as for other medical practices, including but not limited to, the standards for informed consent, delegation to allied health professionals, physician-patient confidentiality, physician-patient boundaries and maintenance of medical records.

Physicians may delegate the injection of Botox Cosmetic and Vistabel to allied health professionals. These allied health professionals should be known by the supervising physician to be capable of performing the specific functions.

A supervising physician (one who oversees, directs, has charge, inspects, and provides guidance and evaluation) should be capable of performing the functions supervised and/or delegated. Direct Supervision (the physician is physically present in the treating facility) is recommended.

Under Section 334.100.2 (4) (d) RSMo, supervising physicians are responsible for the patient’s care. Therefore the supervising physician should ensure that back-up systems (on call) and emergency policies are established.

Additionally, under Section 334.047, RSMo, the supervising physician’s license must be publically displayed in the treating facility. The Board strongly recommends that the hours the physician is available in the facility be publically displayed also.

With respect to “Botox Cosmetic” and “Vistabel” the FDA issued black box warning in May 2009. Thus, it is paramount an adequate medical history is obtained, risk-benefits and side effects are explained in detail, plus the medical history is reviewed by a qualified health care provider before Botox treatment is initiated.

Amended and Adopted by the Missouri Board of Cosmetology and Barber Examiners March 15, 2010.